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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,703	06/27/2000	Markus Pompejus	BGI-129CP	3829
959	7590	03/09/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			MORAN, MARJORIE A.	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34

Office Action Summary	Application No.	Applicant(s)	
	09/605,703	POMPEJUS ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/6/03; 12/3/03.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-42 and 45-61 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☒ Claim(s) 40-42, 46 and 51 is/are allowed.
 6) ☒ Claim(s) 39, 45, 47-50 and 52-61 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20040304</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

All rejections and objections not reiterated below are hereby withdrawn in view of the amendments filed 3/6/03 and 12/3/03. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance.

The prior art neither teaches nor makes obvious an isolated nucleic acid consisting of the full length of SEQ ID NO: 1 or a protein 90% identical SEQ ID NO: 1, or the full complements of these. Nor does the prior art teach or fairly suggest an isolated nucleic acid molecule which encodes a polypeptide comprising or consisting of SEQ ID NO: 2. Claims 40-42, 46, and 51 have utility as the specification discloses that the inventive sequences may be used to detect pathogenic organisms and/or to distinguish pathogenic *Corynebacterium* species from nonpathogenic species.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

35 U.S.C. 112, Written Description Rejection

Claims 39, 45, 47, 49-50 and 52-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK of WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 3/6/03 have been fully considered but they are not persuasive. In response to applicant's argument that a DNA fragment which encodes an ORF

Art Unit: 1631

meets the requirements for written description, it is noted that SEQ ID NO: 1 comprises several possible start codons, and thus may encode several ORFs. SEQ ID NO: 2 is merely one of many possible peptide sequences which may be encoded by a nucleic acid comprising SEQ ID NO: 1, therefore the fact that a single ORF has been disclosed within SEQ ID NO: 1 is not a full and complete description of the genus of nucleic acids represented by the claims. Applicant's arguments with respect to claims directed to an enzyme (catalyst) are moot as (a) the instant claims are not directed to polypeptides, but are directed to nucleic acids, and (b) the polypeptides encoded by the claimed nucleic acids have not been shown to have ANY activity, specifically a catalytic one. With regard to functional arguments, as set forth on page 9 of the response, it is noted that unlike the example presented, the instantly claimed nucleic acids have not been shown to have any activity, per se.

Therefore, only sequences consisting of SEQ ID NO: 1, and sequences which encode a polypeptide consisting of SEQ ID NO: 2, but not the full breadth of the claims, meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

For the reasons set forth above, the rejection is maintained.

Claims 47, 48, 52, and 53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK of WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 3/6/03 have been fully considered but they are not persuasive. The examiner agrees that the specification discloses both SEQ ID NO: 1 and SEQ

Art Unit: 1631

ID NO:2, and provides a definition for an MCP protein or polypeptide. However, nowhere does the specification disclose that SEQ ID NO: 2 is known to actually be capable of modulating the “yield, production, and/or efficiency of production of one or more fine chemicals from C. glutamicum.” The fact that a polypeptide is encoded by a nucleic acid isolated from C. glutamicum does not mean that the polypeptide necessarily comprises modulating activity for yield, production, etc. of fine chemicals. In fact, as it is well known in the art that many genes and proteins required for growth of a cell are redundant, it is possible that a protein may have no effect on yield or production of anything. The specification does not disclose, and no evidence has been presented anywhere, which establishes that SEQ ID NO: 2 has ANY activity, specifically modulatory activity.

For these reasons and those previously set forth, the rejection is maintained.

Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A nucleic acid comprising a fragment of at least “30 contiguous” nucleotides is new matter. The original claims did not recite fragments of at least 30 contiguous nucleotides. The originally filed specification, on page 23, provides support for a nucleotide “of at least 30” nucleotides in length. Nowhere does the originally filed specification disclose fragments of at least 30 contiguous nucleotides. As neither the original claims nor specification provide support for the new limitation of claim 49, the claim is rejected for reciting new matter.

Conclusion

Claims 40-42, 46, and 51 are allowed; claims 39, 45, 47-50 and 52-61 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

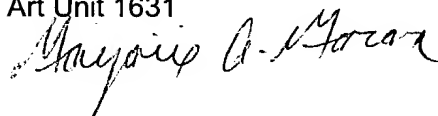
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631



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